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NEDU TR 04-06
February 2004

SUITABILITY OF NONIN MODELS 8500 AND 9500 PULSE OXIMETERS, AND MODEL 9847 PULSE OXIMETER, AND CARBON DIOXIDE DETECTOR FOR USE IN HYPERBARIC CHAMBERS

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REPORT DOCUMENTATION PAGE

1a. REPORT SECURITY CLASSIFICATION Unclassified	1b. RESTRICTIVE MARKINGS
2a. SECURITY CLASSIFICATION AUTHORITY	DISTRIBUTION/AVAILABILITY OF REPORT DISTRIBUTION STATEMENT A: Approved for public release; distribution is unlimited.
2b. DECLASSIFICATION/DOWNGRADING AUTHORITY	
4. PERFORMING ORGANIZATION REPORT NUMBER(s) NEDU TECHNICAL REPORT No. TR 04-06	5. MONITORING ORGANIZATION REPORT NUMBER(S)
6a. NAME OF PERFORMING ORGANIZATION Navy Experimental Diving Unit 6b. OFFICE SYMBOL (If Applicable) 02	7a. NAME OF MONITORING ORGANIZATION
6c. ADDRESS (City, State, and ZIP Code) 321 Bullfinch Road, Panama City, FL 32407-7015	7b. ADDRESS (City, State, and Zip Code)
8a. NAME OF FUNDING SPONSORING ORGANIZATION NAVAL SEA SYSTEMS COMMAND 8b. OFFICE SYMBOL (If Applicable) 00C	9. PROCUREMENT INSTRUMENT IDENTIFICATION NUMBER
8c. ADDRESS (City, State, and ZIP Code) 2531 Jefferson Davis Highway, Arlington, VA 22242-5160	10. SOURCE OF FUNDING NUMBERS PROGRAM ELEMENT NO. / PROJECT NO. / TASK NO. / WORK UNIT ACCESSION NO. 98-010
11. TITLE (Include Security Classification) Suitability of Nonin models 8500 and 9500 pulse oximeters, and model 9847 pulse oximeter, and carbon dioxide detector for use in hyperbaric chambers	
12. PERSONAL AUTHOR(S) Gary W. Latson, CDR, MC, USNR	
13a. TYPE OF REPORT TECHNICAL REPORT 13b. TIME COVERED FROM From 1996 to 2000 14. DATE OF REPORT (YY/MMM/DD) July 2000 15. PAGE COUNT 13	
16. SUPPLEMENTARY NOTATION	
17. COSATI CODES FIELD / GROUP / SUB-GROUP	18. SUBJECT TERMS (Continue on reverse if necessary and identify by block number) Pulse oximeters, respiratory adequacy, critical care settings, hyperbaric chambers, arterial oxygen saturation, carbon dioxide detectors

19. ABSTRACT:

Pulse oximetry has proven to be a valuable clinical monitor of respiratory adequacy in many healthcare settings. It is considered to be "standard of care" in many critical care settings such as operating rooms, intensive care units, and procedure rooms where sedation is administered. Although most patients in hyperbaric chambers are well oxygenated by virtue of the fact that they are breathing oxygen at hyperbaric pressures, some situations could result in hypoxemia, such as airway compromise, pneumothorax, aspiration pneumonitis or pulmonary edema. Therefore, a simple, rapid, noninvasive means of determining arterial oxygen saturation would be valuable. Pulse oximetry offers these advantages if the instrument is shown to be suitable for use in the hyperbaric environment. Additionally, measurement of expired carbon dioxide can serve as a valuable means of assessing adequacy of ventilation and verification of placement of airway devices. The Model 9847 incorporates both a pulse oximeter and infrared carbon dioxide analyzer into one compact unit.

20. DISTRIBUTION/AVAILABILITY OF ABSTRACT | | UNCLASSIFIED/UNLIMITED |X| SAME AS RPT. | | DTIC USERS	21. ABSTRACT SECURITY CLASSIFICATION Unclassified	
22a. NAME OF RESPONSIBLE INDIVIDUAL NEDU Librarian	22b. TELEPHONE (w/Area Code) (850) 230-3100	22c. OFFICE SYMBOL

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INTRODUCTION

Pulse Oximetry has proven to be a valuable clinical monitor of respiratory adequacy in many healthcare settings. It is considered to be "standard of care" in many critical care settings such as operating rooms, intensive care units, and procedure rooms where sedation is administered. Although most patients in hyperbaric chambers are well oxygenated by virtue of the fact that they are breathing oxygen at hyperbaric pressures, some situations could result in hypoxemia, such as airway compromise, pneumothorax, aspiration pneumonitis or pulmonary edema. Therefore, a simple, rapid, noninvasive means of determining arterial oxygen saturation would be valuable. Pulse oximetry offers these advantages if the instrument is shown to be suitable for use in the hyperbaric environment.

Additionally, measurement of expired carbon dioxide can serve as a valuable means of assessing adequacy of ventilation and verification of placement of airway devices. The Model 9847 incorporates both a pulse oximeter and infrared carbon dioxide analyzer into one compact unit.

METHODS

PRODUCT SELECTION

To our knowledge, prior to 1999 no commercially available pulse oximeter had been formally evaluated by the U.S. Navy for use in hyperbaric chambers. The Medical Department at Navy Experimental Diving Unit decided to select a commercially available unit and evaluate it. We surveyed the market by reviewing the units listed in several catalogs of medical supply vendors. Desirable features included small size and low weight, durable construction, availability of a variety of sensor configurations, and an alkaline battery power source, because commercially available alkaline batteries have already been approved for use in U.S. Navy hyperbaric chambers. Several models seemed to fit the desired characteristics, but there were no funds available to test multiple units. The Ohmeda model 3775 was chosen due to familiarity among the medical officers and the wide availability of the Ohmeda brand. That unit was tested and found to be suitable for hyperbaric use up to 165 fsw[1].

Subsequent to that, several models of pulse oximeters made by Nonin Medical Inc. gained our attention due to their small size and prior testing by the U.S. Air Force for aeromedical transport. It was felt that these models would also be suitable for hyperbaric use, and thus they were chosen for testing. The Model 9847 has the added capability of carbon dioxide analysis.

EVALUATION

The units were inspected by electronics technicians knowledgeable about instrumentation in hyperbaric environments. No obvious fire hazards or potentially vulnerable components were identified. The units were then subjected to hyperbaric pressure up to 165 fsw in an unmanned test chamber (see attachment) with a check on the units function before and after each dive. This consisted of five cycles of pressurization on air to 165 fsw for 5 minutes, followed by depressurization. The units were verified to be functional after each cycle. The units were not subjected to "off gas" testing because it was deemed unnecessary based on inspection and comparison to prior testing of similar instruments.

Functional testing of the Model 9847 was performed in a hyperbaric chamber at pressures of 30,60, and 165 fsw to evaluate the carbon dioxide detector. Calibration gases with known concentrations of carbon dioxide, and expired breath from one investigator, were tested at each depth and compared to readings obtained at the surface for these same gases, and the function of the oximeter was tested

RESULTS

1. Bench testing and internal inspection revealed no electrical safety hazards (see Appendix A).

2. The units functioned properly at a pressure of 165 fsw, and no change was noted in performance upon return to surface pressure (see Appendix A).

3. The carbon dioxide detector functioned within specifications at surface pressure (see Appendix A).

4. During manned operation of the Model 9847, it was noted that the flexible covering over the switches on the front of the unit collapsed during rapid compression, causing the unit to turn off. This was easily corrected by making a puncture in the cover with a small needle, which allowed the venting of the closed space behind the cover. The unit operated normally after this procedure. Pulse oximetry values at depth were 98 to 100%, which is consistent with values obtained on the surface and expected with the increased levels of inspired oxygen at depth.

5. Analysis of gases at depth provided the following results:

Surface:

Gas	mmHg CO_2	Instrument Display
3% CO_2	22.8	20
5.1% CO_2	38.8	30
Expired	variable	50 to 75

30 fsw:

Gas	mmHg CO_2	Instrument Display
3% CO_2	43.5	50
5.1% CO_2	74	75
Expired	variable	50 to 75

60 fsw:

Gas	mmHg CO_2	Instrument Display
3% CO_2	64.3	75
5.1% CO_2	109	>75
Expired	variable	>75

165 fsw:

Gas	mmHg CO_2	Instrument Display
3% CO_2	136.8	>75
5.1% CO_2	232.6	>75
Expired	variable	50 to 75

DISCUSSION

There were no problems noted with the oximeter function of any of the units tested, other than need to puncture the flexible cover on the front of the Model 9847 to equalize the gas containing space after rapid compression.

The performance of the CO_2 detector in the Nonin Model 9847 met our expectations. Accuracy on surface was within stated specifications. The manufacturer notes in the Operator's Manual that the readings are only a semi-quantitative indication of breath to breath change in expired CO_2, and notes that the accuracy is not intended to be comparable to a capnograph. It is intended for confirmation of airway placement, monitoring of respiratory rate, and as an indicator of respiratory adequacy.

Testing at depth showed a slight trend toward elevated readings, which is consistent with known effects of depth on infrared CO_2 sensing technology. The magnitude of this error at depth was relatively small, and difficult to fully quantify due to the manner in which the CO_2 level is displayed on a bar graph with large and irregular increments (2, 6, 10, 20, 30, 50, 75, and >75 mmHg). Specifically, the sample containing 3% CO_2 resulted in a reading of 50 mmHg on the instrument at 30 fsw when the true value at that depth was 43.5 mmHg CO_2, and the instrument gave a reading of 75 mmHg at 60 fsw when the true value at that depth was 64.3 mmHg. In effect, the instrument read one bar graph increment higher than expected, but the true values were between the incremental thresholds, and thus the actual error may have been smaller.

The readings obtained by the investigator expiring through the instrument were mostly consistent with the values obtained at the surface. The only reading that seemed erroneously high was obtained at 60 fsw where the instrument read >75 mmHg compared to surface readings of 50 or 75 mmHg. It is possible that the investigator had a slight physiologic increase in CO_2 at that depth, which when combined with a small error in the instrument resulted in the display reading the next higher incremental value. In the opinion of the investigator, this small magnitude of error does not negate the clinical usefulness of the device for confirmation of airway placement and adjustment of minute ventilation in an intubated patient, but users of the device should be aware that the values displayed may be higher than expected. In a clinical setting, the practitioner could measure his own expired breath (or a known calibration gas) at depth for comparison to the patient.

CONCLUSION/RECOMMENDATION

In our opinion, the Nonin Model Pulse Oximeter Models 8500 and 9500, and sensors, and the Model 9847 Pulse Oximeter and Carbon Dioxide Detector are safe for hyperbaric treatment chamber use up to a pressure of 165 fsw. We recommend it be approved for use in U.S. Navy hyperbaric chambers up to 165 fsw. Although we do not suspect that accuracy of the pulse oximeter instrument will be affected by pressure, this has not been verified extensively in human use. Venting of the flexible front cover of the Model 9847 may be necessary with rapid compression. There is reason to believe the infrared carbon dioxide detector readings may vary with depth, with a tendency toward erroneously high values, but the magnitude of this error is small and can be easily accounted for in clinical use. Actual clinical use should provide a basis for determining if further studies are needed in this area.

REFERENCES

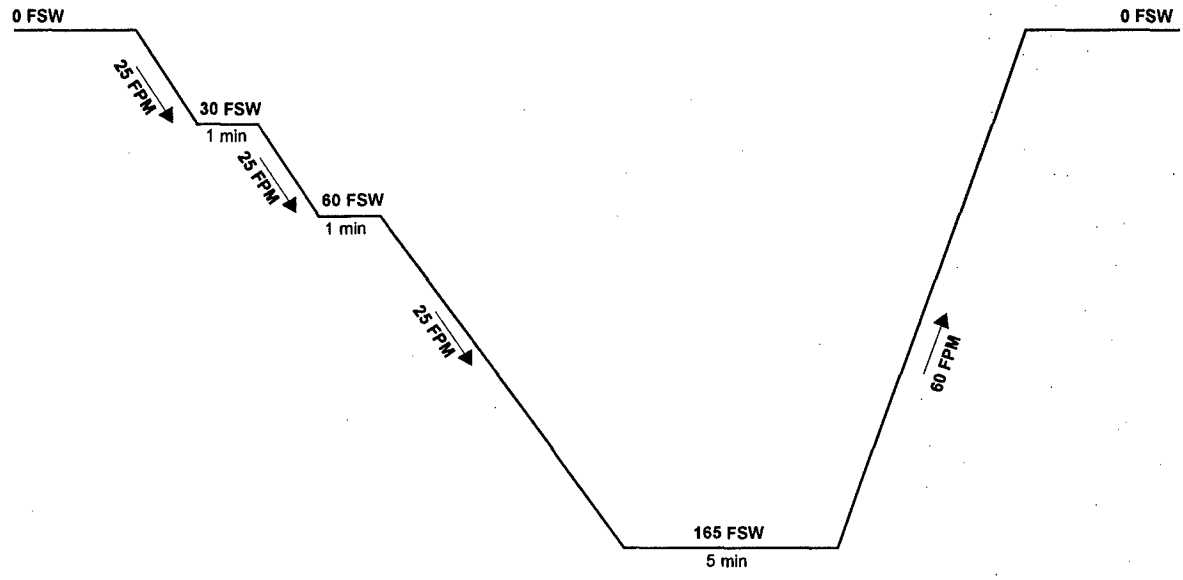
1. Latson, G. W., *Suitability of Ohmeda Model 3775 Pulse Oximeter for use in Hyperbaric Chambers*, NEDU MDTN 99-03, Navy Experimental Diving Unit, November 1999.

Appendix A

To: Mr. Jack Schmitt 13 December 1999
From: R.J. Steckel
Subj: NONIN Oximeter Test

Pressure testing of three Nonin Oximeters models 9874 (Pulse Oximeter and CO_2 Detector), 9500 (Finger Pulse Oximeter), and 8500 (Handheld Pulse Oximeter) was conducted according to the following dive profile. This test was a pressure and functions test only, not an accuracy or calibration test. Each model was cycled through the profile 5 times using an atmosphere of air. After each dive, each oximeter was checked by placing the oximeter sensor on the right index finger as a check for comparison purposes. The CO_2 sensor on Model 9874 was checked by exhaling near the sensor. The results were comparable and the data are presented in the table.

Dive Profile for NONIN Oximeters



TEST #	MODEL #	% SpO_2	Pulse	CO_2
Predive readings	9874	97	60	OK
	9500	97	61	n/a
	8500	97	64	n/a
1	9874	98	64	OK
	9500	97	64	n/a
	8500	98	60	n/a
2	9874	97	61	OK
	9500	98	60	n/a
	8500	99	60	n/a
3	9874	98	60	OK
	9500	98	63	n/a
	8500	99	65	n/a
4	9874	98	60	OK
	9500	99	62	n/a
	8500	99	69	n/a
5	9874	98	65	OK
	9500	98	62	n/a
	8500	98	65	n/a

To: Mr. J. Schmitt, code 03 10 July 2000
Fm: R.J. Steckel
Subj: "NONIN" Pulse Oximeter/ Carbon Dioxide Detector Evaluation

The NONIN Model 9847 Pulse Oximeter and Carbon Dioxide Detector is designed to measure and display oxygen saturation of blood hemoglobin (SpO_2), pulse rate and *approximate* carbon dioxide level changes in the airway of *intubated* patients.

This instrument was previously evaluated for hyperbaric chamber use by NEDU code 02 personnel and found to be suitable for use for measurements of SpO_2 and pulse rate. The instrument has passed pressure testing to a maximum depth of 165 FSW in an air environment.

The object of this evaluation was to determine the functionality of the carbon dioxide detector. The manufacturer specifications list the CO_2 detection range as 0-75mmHg (0-9.9% SEV).

Unlike previously evaluated CO_2 monitors/detectors, this model detects the *change* in CO_2 as the respiration cycle occurs, and displays the result by lighting portions of an 8 segment LED bar graph on the instruments face. The accuracy of this bar graph is stated to be ± 25% of the segment illuminated.

As the instrument electronics are programmed to detect a *change* in CO_2 levels between that of clean inspired gas and CO_2 ladened expired gas, unmanned testing was conducted at 1 atmosphere (1 ATA).

The CO_2 sensor was rapidly transferred from room atmosphere to a container of certified calibration gas, then back to room atmosphere. The LED bar graph reading was recorded, and the trial repeated. Table 1 presents the average result of 30 trials.

Table 1 – Instrument performance at 1 ATA

Calibration Gas	CO_2 Content (mmHg)	Instrument Display (mmHg)
1.47% CO_2/Balance N_2	11.17	10
2.49% CO_2/Balance He	18.90	20
1.47% CO_2/Balance N_2	11.17	10

These results show the instrument performs within the manufacturers specifications for detection of CO_2 change.

It is recommended that manned evaluations of this instrument be conducted.